

September 4, 2002

Doug Anderson
Higher Olefins Panel Manager
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. Anderson:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for 1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated posted on the ChemRTK HPV Challenge Program Web site on January 29, 2002. I commend the American Chemistry Council Higher Olefins Panel, Polyalphaolefins Task Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The American Chemistry Council Higher Olefins Panel, Polyalphaolefins Task Group advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated**

SUMMARY OF EPA COMMENTS

The sponsor, American Chemistry Council Higher Olefins Panel, Polyalphaolefins Task Group, submitted a test plan and robust summaries to EPA for 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated (decene tetramer/trimer) (CAS No. 68649-12-7) dated December 18, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 29, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. The submitter proposes to use four closely related analogs to address the ecotoxicity and health endpoints, and to supplement the physicochemical endpoints for decene tetramer/trimer. Based on their close structural similarity, EPA agrees with the use of data on the analogs to address the decene tetramer/trimer data gaps.
2. Physicochemical Properties and Environmental Fate. (a) EPA agrees with the submitter's proposal to use a combination of calculated and measured data to address the physicochemical endpoints. (b) EPA agrees with the submitter's proposal to calculate photodegradation and fugacity. However, EPA prefers the Level III fugacity model. (c) EPA agrees that a stability in water test is not necessary due to the absence of hydrolyzable functional groups. (d) EPA agrees that the biodegradation endpoint has been adequately addressed.
3. Health Effects. All appropriate SIDS-level tests have been addressed with analog data.
4. Ecological Effects. EPA believes that aquatic testing is not necessary because the water solubility is sufficiently low.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

**EPA COMMENTS ON THE 1-DECENE, TETRAMER, MIXED WITH 1-DECENE TRIMER,
HYDROGENATED CHALLENGE SUBMISSION**

Test Plan

Analog Justification

The submitter proposes to use data on four analogs of decene tetramer/trimer to address the ecotoxicity and health effects endpoints, and to supplement the physicochemical data. All the substances are long-chain branched alkanes. Decene tetramer/trimer is primarily a C30 oligomer (~85%), with a C40 oligomer comprising most of the remainder. The analogs are similar long-chain branched alkanes derived from C8, C10, and/or C12 alpha olefins; decene homopolymer, decene/dodecene copolymer, octene/decene/dodecene copolymer, and dodecene trimer. The submitter supports the use of the analogs by comparing data on all the ecotoxicity and health effects endpoints. Given the similar molecular structure and comparable effects data, EPA agrees that the four substances are acceptable analogs for decene tetramer/trimer.

Chemistry (melting point, boiling point, vapor pressure, partition coefficient, and water solubility).

The submitter's approach to these endpoints, with the clarification for water solubility noted below, using a combination of measured and calculated data from decene tetramer/trimer and the analogs is acceptable for the purposes of the HPV Challenge Program.

Water Solubility. The submitted measured value of < 0.4 ppm was for 1-octene, 1-decene, 1-dodecene copolymer (hydrogenated), an analogous chemical. It might contain some low molecular weight oligomer fractions that could lead to a higher water solubility value. Therefore, EPA suggests that the submitter not use this value but instead use an estimated method (i. e., WSKOW v1.33) to obtain water solubility for this mixture since the estimated value is well below the OECD guideline of 1 ppb.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA agrees with the submitter's approach for photodegradation and stability in water. The biodegradation data are adequate in this specific case, but the test method used is less informative than other methods and is generally not recommended. The description of the test results in the test plan should conform to the conclusion presented in the robust summary.

Biodegradation. Although a less than optimal test method was used for the biodegradation test, this is mitigated by the very low water solubility of the substance and the lack of acute ecotoxicity and predicted no chronic toxicity. However, the submitter's claim in the test plan that the substance can "biodegrade to a great extent" is not supported by the data. The robust summary properly characterizes the material as not readily biodegradable. The submitter's test plan statement more closely approximates a finding of ready biodegradability, which the data do not support.

Fugacity. The sponsor proposes to estimate the fugacity of these chemicals using a Level I EQC model. Although EPA had previously recommended the use of Level I, this model is somewhat limited. EPA now recommends a Level III analysis, which is more rigorous. The EQC and EPIWIN Level III models are acceptable.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate test data on the analogs are available to address these endpoints for decene tetramer/trimer for the purposes of the HPV Challenge Program. The submitter needs to supply a robust summary for the reproductive toxicity endpoint-examination of the sex organs in the repeated-dose studies. HPV Challenge Program guidance states that when adequate histopathologic examination of reproductive organs in existing repeated-dose studies is documented and an adequate developmental toxicity study is available, the reproductive/developmental toxicity endpoint can be considered addressed. Also, when a study addresses multiple endpoints, a robust summary is needed for each endpoint.

Ecotoxicity (fish, invertebrates, and algae).

EPA believes that no additional testing is necessary because the chemical is too insoluble in water (# 1ppt for lowest limit of quantification using analog CAS No. 151006-62-1). At this low water solubility no chronic effects are expected. Therefore, the fact that the aquatic effect tests were all done above the analogs' aqueous water solubility limits and at the acute #96-hours duration, rather than the acceptable long-term chronic duration of 21 days, is not an issue.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.